JUN 2 1 2000

K001269

XI. 510(k) SUMMARY (OF SAFETY AND EFFECTIVENESS). April 15, 2000. [Separate Pages]

A. Submitted by: Eric Dupinet, Dentalmatic Technologies, Inc., St. Laurent, Quebec, H4S3V9, Canada. Phone: 514-337-1444

I. Classification Names and numbers: Base Metal Alloy, 76EJF, Class II and Porcelain Powder for Clinical Use, 76EIH, Class II.

II. Common/Usual Name: Base metal alloy, Porcelain powder

III. Proprietary Names: Dentalmatic Ti/Ti-A Prosthetic™

IV. Establishment Registration Number: Foreign, in process

V. Classification: These are Class II devices, intended to restore carious lesions or structural defects in teeth or to replace teeth, described in CFR 872.3710 and CFR 872.6660. Like base metal alloy and porcelain powder products, this device is delivered in final form for use by the dentist.

VI. Device Description: Dentalmatic plans to sell to **dental laboratories** two products; an optical scanner with a computer/monitor/design software and (2) a milled titanium prosthesis fabricated to the laboratories specifications. The optical scanner is used by the dental lab to digitally replicate a dental cast which was fabricated by the laboratory from a **dental impression obtained from the dentist (patient)**. The laboratory utilizes digital prosthetic tools contained in the CAD (computer aided design) software system. These computer tools are similar to the tools used in traditional lab techniques to design the "base" prosthesis restoration (crown or coping) in accordance with the **dentists prescription** and laboratory standards. The laboratory, once satisfied with the design of the metal substructure base, closes out the design and submits the design work order to Dentalmatic for titanium fabrication of the base restoration. The order is milled on a CNC milling machine at Dentalmatic, is then cleaned, inspected, packaged and shipped to the laboratory. Upon receipt of the milled coping or crown, the laboratory inspects for quality acceptance, and then continues with the restoration process of applying restorative materials such as dental opaque and porcelains over the base titanium surface. The laboratory would follow normal procedures in completing the prosthesis following receipt of the milled crown or coping from Dentalmatic.

VII. Substantial Equivalence: Relative to devices currently on the market, cleared by the 510(k) process, Dentalmatic™ is substantially equivalent and quite similar to "P10 Special" cleared by North American Alloys, Inc. in K-993344, to "Vitallium 2000 Alloy and Plus Alloy", cleared by Austenal, Inc. in K-970205. For some of its proposed uses, it also is substantially equivalent to porcelain powders (code EIH, CFR 872-6660)--ceramic products such as "3M TR System," cleared in K-992489; to "Vita Titanium Porcelain," cleared by Vident in K-982664, and to "Finesse All-Ceramic System" cleared by Dentsply, Intl., in K-971869 and their "Dental

Ceramic" cleared in K-830955.
The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as prostheses to be cemented or luted into place as inlays, onlays, veneers, crowns or partials for the repair of damaged or missing teeth.

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market. In addition, the technological differences are well understood in the dental industry. The use of a computerized lathe system to prepare the prostheses in the dental laboratory or supplier also has been cleared by 510(k)--K950299, and K972276.

3. Descriptive information provided shows that the materials from which this device is made are well-established in the more damanding areas of dental implants. They resemble the properties of finished base metal alloy and porcelain products, as well.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment III.

VIII. Intended Use: Intended use is for the preparation of crowns, facings, veneers, inlays and onlays-to produce a hard prosthesis with a titanium or porcelain-like finish. Also for fabricating copings and frameworks for inlays, onlays, veneers, crowns, anterior and posterior bridge restorations.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2000

Mr. Eric Dupinet
Senior Technical Manager
Dentalmatic Technologies, Incorporated
9710 Transcanada Highway
St. Laurent, Quebec, H4S 1V9,
CANADA

Re: K001269
Trade Name: Dentalmatic Ti Prosthetic™ and Dentalmatic Ti-A Prosthetic™
Regulatory Class: II
Product Code: EJH
Dated: April 18, 2000
Received: April 20, 2000

Dear Mr. Dupinet:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001269

VIII.1 Indications for Use: [Separate Page]

510(k) Number: K001269

Device Name: Dentalmatic Ti/Ti-A Prosthetic™

Indications for use:

Intended for preparation of crowns, facings, veneers, inlays and onlays--to produce a hard prosthesis with a titanium or porcelain-like finish.

For fabricating copings and frameworks for inlays, onlays, veneers, crowns, anterior and posterior bridge restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓
(Per 21 CFR 801.109

OR

Over-The-Counter Use____
(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001269